

**DEPARTMENT OF HEALTH & HUMAN SERVICES**Food and Drug Administration
Public Health Service**2/8/2016****FOIA 2016-277**

Dear Requestor,

The attached record(s) are being provided by the Office of Regulatory Affairs (ORA), New Orleans District (NOL-DO), in response to your request dated 01/12/16 for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

**RECS RE FDA WARNING LETTER TO DEWMAR INTERNATIONAL BRAND MANAGEMENT
03/01/2013-01/10/2016**

Your request is granted in part.

After a thorough review of the responsive records, we have determined that portions of the documents are exempt from disclosure under FOIA exemptions (b)(4), (b)(6), and b(7) of the FOIA 5 U.S.C. § 552, as amended and delineated below:

- Exemption (b)(4) permits the withholding of "trade secrets" (TS) and "commercial confidential information" (CCI). Disclosure of this information would impair the government's ability to obtain necessary information in the future and cause substantial harm to the competitive position of the person from whom the information was obtained. Under the balancing test of this exemption, we are withholding all proprietary information identified as TS and CCI.
- Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth, under exemption (b)(6), to release the personal identifying information of certain third parties.
- Exemption (b)(7) protects from disclosure "records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information (A) could reasonably be expected to interfere with enforcement proceedings, (B) would deprive a person of a right to a fair trial or an impartial adjudication, (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy, (D) could reasonably be expected to disclose the identity of

a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source, (E) would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or (F) could reasonably be expected to endanger the life or physical safety of any individual.

Please be advised that your request may have been submitted to one or more component offices within FDA. These offices will reply to you directly. NOL-DO considers your request closed.

If you have reason to believe that the information withheld should not be exempt from disclosure, you may appeal. Your appeal should be sent within 30 days from the date of this letter. Your appeal should include copies of your original request and this response, as well as a discussion of the reasons supporting your appeal. The envelope and letter should be plainly marked to indicate that it contains a FOIA appeal and include the control number. If you decide to appeal this determination, your appeal should be sent to:

Deputy Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services,
Room 19-01, 5600 Fishers Lane
Rockville, MD 20857

If you have any questions about this response, you may contact Melissa Williams at 615-366-7804.

Please do not submit payment until you receive an invoice. The following charges for this request to date may be included in a monthly invoice:

Reproduction=\$0.00 Search=\$11.50 Review \$23.00 Other \$0.00 Total=\$34.50

Sincerely,



Melissa C. Williams
ORA FOI Officer
New Orleans District

Enclosure(s)